

### REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1-3, 8-10 and 13 are pending. Non-elected claims 1-7 were withdrawn from consideration by the Examiner. Claims 4-7 have been canceled without prejudice or disclaimer to their later prosecution. Rejoinder of process claims 1-3 is requested upon allowance of a product claim.

The Examiner's acknowledgement of Applicants' claim for foreign priority under 35 U.S.C. 119 is also requested.

Substitute paper and computer readable forms of the Sequence Listing are being submitted herewith in response to the Examiner's requirement. The paper and computer readable forms of the Sequence Listing do not add new matter, and their contents are the same. It is respectfully submitted that this submission complies with 37 CFR § 1.821 et seq. Otherwise, prompt notice of any defects in the Sequence Listing is earnestly solicited and additional time is requested to comply.

#### *Claim Objection*

Claims 10-14 were objected to. The Examiner's suggestion has been adopted to moot the objection.

Withdrawal of the objection is requested.

#### *35 U.S.C. 112 – Definiteness*

Claim 11 was rejected under Section 112, second paragraph, as being allegedly "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Applicants traverse because claim 11 has been canceled.

Applicants request withdrawal of the Section 112, second paragraph, rejection because the pending claims are clear and definite.

*35 U.S.C. 102 – Novelty*

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 10 and 13 were rejected under Section 102(e) as allegedly anticipated by Lee et al. (WO 01/31061). Applicants traverse because claims 10 and 13 are not drawn to SEQ ID NO:3.

Withdrawal of the Section 102 rejection is requested because all limitations of the claimed invention are not disclosed by the cited reference.

*35 U.S.C. 103 – Nonobviousness*

To establish a case of prima facie obviousness, all of the claim limitations must be taught or suggested by the prior art. See M.P.E.P. § 2143.03. Obviousness can only be established by combining or modifying the prior art teachings to produce the claimed invention if there is some teaching, suggestion, or motivation to do so found in either the references themselves or in the knowledge generally available to a person of ordinary skill in the art. See, e.g., *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *In re Jones*, 21 USPQ2d 1941, 1943-44 (Fed. Cir. 1992). It is well established that the mere fact that references can be combined does not render the resultant combination obvious unless the desirability of that combination is also taught or suggested by the prior art. See *In re Mills*, 16 USPQ2d 1430, 1432 (Fed. Cir. 1990). Thus, even if all elements of the claimed invention were known, this is not sufficient by itself to establish a prima facie case of obviousness without some evidence that one would have been motivated to combine those teachings in the manner proposed by the Examiner. See *Ex parte Levengood*, 28 USPQ2d 1300, 1302 (B.P.A.I. 1993).

Evidence of the teaching, suggestion or motivation to combine or to modify references may come explicitly from statements in the prior art, the knowledge of a

person of ordinary skill in the art or the nature of the problem to be solved, or may be implicit from the prior art as a whole rather than expressly stated in a reference. See *In re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999); *In re Kotzab*, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000). Rigorous application of this requirement is the best defense against the subtle, but powerful, attraction of an obviousness analysis based on hindsight. See *Dembiczak* at 1617. Whether shown explicitly or implicitly, however, broad conclusory statements standing alone are not evidence because the showing must be clear and particular. See *id.*

Claims 8-9 and 13-14 were rejected under Section 103(a) as allegedly unpatentable over Lee et al. (WO 01/31061). Applicants traverse.

In the present invention, the pair of oligonucleotide primers having the sequences described by SEQ ID NOS:1 and 2 were designed to amplify a 531bp fragment of the mycobacterial *rpoB* gene. By amplifying the 531bp fragment of the *rpoB* gene, it is possible to identify *Mycobacterium tuberculosis* and MOTTs simultaneously to determine susceptibility of the *Mycobacterium tuberculosis* to antituberculosis drug in one step, with one or more of the oligomer probes selected from the group consisting of SEQ ID NOS:3 to 20.

The primer B-5' (SEQ ID NO:1) was designed to amplify the 531bp fragment of the *rpoB* gene which is used for identifying *Mycobacterium tuberculosis* and MOTTs and determining susceptibility of the *Mycobacterium tuberculosis* to antituberculosis drug simultaneously at one step. In contrast, the cited reference WO 01/31061 does not disclose a method or primer for identifying *Mycobacterium tuberculosis* and MOTTs and determining susceptibility of the *Mycobacterium tuberculosis* to antituberculosis drug simultaneously. The primer RPO5' of WO 01/31061 is not identical to SEQ ID NO:1 and there is neither teaching nor suggestion in the cited reference to modify the nucleotide sequence of primer RPO5' to be SEQ ID NO:1. In the absence of such teaching or suggestion, Applicants submit that one of ordinary skill in the art would not have been motivated to design the primer B-5' of the claimed invention from the primer RPO5' of WO 01/31061.

Withdrawal of the Section 103 rejection is requested because the invention as claimed would not have been obvious to a person of ordinary skill in the art at the time it was made.

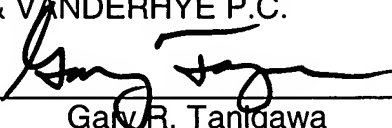
*Conclusion*

Having fully responded to all of the pending objections and rejections contained in the Office Action (Paper No. 12), Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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